510(K) SUMMARY - #K060186
(as required by 807.92(c))

JUL 18 2006

Submitter of 510(k):

TE ME NA SAS
16, Rue Des Entrepreneurs
Carriere Sur Seine, FRANCE 78420

Phone: 011-331-30860530

Contact Person: Wilhelm Waskonig

Date of Summary: January 3, 2006

Trade/Proprietary Name: Polyplex Stimulating Catheter System

Classification Name: Catheter, Conduction, Anesthetic

Product Code: BSO, CAZ

Device Description:

The Polyplex Stimulating Catheter System is an anesthesia conduction catheter that is electrically conductive. Using peripheral nerve stimulation, the clinician can locate specific nerves or nerve plexuses for continuous nerve block anesthesia or analgesia.

The Polyplex Stimulating Catheter System is available sterile in a kit with the necessary accessories required to perform the procedure and fix the catheter in place.

Predicate Device:

Te me na – Polymedic Epidural Anesthesia Catheter K991259
Arrow International – StimuCath Continuous Nerve Block Set K021567

Substantial Equivalence:

Te me na claims the proposed device system to be substantially equivalent to the devices previously cleared by FDA in K991259 and K021567. The modifications to the predicate have been described in Section 5 of this submission. Te me na claims this equivalence be cause the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational and biological specification as compared to the predicate devices.

The similarities and differences between the proposed and predicate devices have been identified and explained in the Comparison Matrix which has been included in Section 9 of this submission. These differences have no effect on safety and effectiveness.

Intended Use:

The Te me na POLYPLEX Stimulating Catheter System is intended for placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Te Me Na Sas
C/O Mr. Arthur Ward
RMS Regulatory & Marketing Services, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K060186
Trade/Device Name: Polyplex Stimulating Catheter System
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: July 10, 2006
Received: July 13, 2006

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

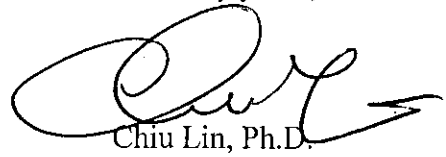
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K060186**

Device Name: POLYPLEX Stimulating Catheter System

Indications for Use:

The Te me na POLYPLEX Stimulating Catheter System is intended for placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K060186